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EXAMINER				
BADR, HAMID R				
ART UNIT		PAPER NUMBER		
1781				
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08/03/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/587,864

Applicant(s)

COLAVIZZA ET AL.

Examiner

HAMID R. BADR

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' amendment filed 6/16/2011 is acknowledged.

Rejection of claim 27 under 35 U.S.C. 112 second paragraph is withdrawn per applicants amendment.

Rejection of claims 17-19 under 35 U.S.C. 102(a) is withdrawn per Applicants remarks.

Claims 17-42 are being considered on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 17-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (1994, Construction from a single parent of Baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1) in view of Hill (US 4, 318,991; hereinafter R2).

3. R1 investigates the hybridization process for generating hybrid *Saccharmyces cerevisiae* strains highly resistant to high sugar content in bread doughs. The hybrid baker's yeast strains as developed through hybridization can efficiently ferment doughs containing 30% sugar (Abstract, Materials and

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Methods, Table 1). R1 discloses the preparation of doughs using the developed strains. (Ingredients of doughs, Table 1 and dough raising test. Page 3500, col. 1). Given that R1 discloses yeast strains which can efficiently ferment doughs containing 30% sugar, it is obvious that these strains meet the requirement of claim 27 reciting the dough containing 15% sugar.

4. R1 is silent regarding the tolerance of the developed strains to preservatives (mold inhibitors) such as propionates and sorbates and also the preparation of various forms of baker's yeast.

5. R2 discloses a method in which baker's yeast is propagated in the presence of carboxylic acids having 2-4 carbon atoms such as propionic acid. Such baker's yeast is claimed to tolerate the antifungal carboxylic acids (e.g. propionic) during dough fermentation. (Col. 4, lines 13-33). Given that R2 discloses the propagation of baker's yeast in the presence of carboxylic acids having 2-4 carbon atoms, the requirements of claims 23 and 42 are met.

6. R2 also discloses a process for the preparation of compressed yeast and dry baker's yeast. (Col. 3, Lines 55-68). Therefore, claim 24, requiring the preparation of yeast creams, compressed yeast, and dry yeast, would be obvious.

7. It is also noted that calcium propionate has been known and used as antifungal compound in the baking art for a long time. Therefore, claim 28 which requires the presence of mold inhibitors would be obvious.

8. Despite the fact that applicants have provided specific deposit names (I-2971, I-3142, I-3143) for the isolated strains disclosed and claimed, this does not

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provide a patentable distinction over those strains disclosed by R1 as also possessing high sugar and freeze tolerance, absent any clear and convincing evidence and/or arguments to the contrary. The USPTO does not possess the facilities to test each strain of microorganism. However, a reasonable rejection has been set forth and thus the burden shifts to applicant to demonstrate that the strain of the reference is not, in fact, the same as that of the claimed strain. Alternatively, given the specific teachings of R1; one would have been motivated to produce high sugar and freeze tolerant strains through utilization of standard techniques such as hybridization and mutation as known in the art, expecting to screen out strains having high sugar and freeze tolerance.

9. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to develop hybrids of baker's yeast to tolerate high sugar concentration in bread dough as disclosed by R1 and propagate such strains in the presence of carboxylic acids having 2-4 carbon atoms such as propionic acid as taught by R2. One would do so to acquire both high sugar tolerance and preservative tolerance in baker's yeast. Absent any evidence to contrary and based on the combined teachings of the cited references there would have been a reasonable expectation of success in developing the claimed *Saccharmyces cerevisiae* strains.

10. **Claims 17-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ando et al. (US 6,521,272; hereinafter R3) in view of Hill (US 4, 318,991; hereinafter R2).**

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11. R3 discloses yeast to be tolerant to ultra-high sugar range, as well as high sugar and freeze tolerance yeasts. (Abstract)

12. R3 discloses the highly osmotolerant yeasts capable of sufficiently fermenting dough at a very high sugar concentration, such as dough containing sucrose in an amount of 30-50% baker's percent. (col. 6, Table 2 and the paragraph below, and Example 6)

13. R3 discloses one of the sugar tolerant strains to be P-731 (FERM BP-7035). (col. 3, lines 44-45). Also disclosed is P-712 tolerant to sucrose above 30-40 baker's percent. (col. 3, lines 7-9)

14. R3 discloses the methods of obtaining such osmotolerant yeasts (col. 3, lines 20-45).

15. R3 discloses methods of producing dough and bread thereof. (col. 4, line 64 to col. 5 line 2, and Example 2)

16. R3 discloses the method of propagating their inventive yeast. (col. 5, Example 1)

17. R3 is silent regarding the adaptation of yeast culture in the presence of carboxylic acids having 2-4 carbon atoms.

18. R2 discloses a method in which baker's yeast is propagated in the presence of carboxylic acids having 2-4 carbon atoms such as propionic acid. Such baker's yeast is claimed to tolerate the antifungal carboxylic acids (e.g. propionic) during dough fermentation. (Col. 4, lines 13-33). Given that R2 discloses the propagation of baker's yeast in the presence of carboxylic acids having 2-4 carbon atoms, the requirements of claims 23 and 42 are met.

19. R2 also discloses a process for the preparation of compressed yeast and dry baker's yeast. (Col. 3, Lines 55-68). Therefore, claim 24, requiring the preparation of yeast creams, compressed yeast, and dry yeast, would be obvious.

20. It is also noted that calcium propionate has been known and used as antifungal compound in the baking art for a long time. Therefore, claim 28 which requires the presence of mold inhibitors would be obvious.

21. Despite the fact that applicants have provided specific deposit names (I-2971, I-3142, I-3143) for the isolated strains disclosed and claimed, this does not provide a patentable distinction over those strains disclosed by R3 as also possessing high sugar and freeze tolerance, absent any clear and convincing evidence and/or arguments to the contrary. The USPTO does not possess the facilities to test each strain of microorganism. However, a reasonable rejection has been set forth and thus the burden shifts to applicant to demonstrate that the strain of the reference is not, in fact, the same as that of the claimed strain.

Alternatively, given the specific teachings of R3; one would have been motivated to produce high sugar and freeze tolerant strains through utilization of standard techniques such as hybridization and mutation as known in the art, expecting to screen out strains having high sugar and freeze tolerance.

22. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to develop hybrids of baker's yeast to tolerate high sugar concentration in bread dough as disclosed by R3 and propagate such strains in the presence of carboxylic acids having 2-4 carbon atoms such as

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propionic acid as taught by R2. One would do so to acquire both high sugar tolerance and preservative (i.e. calcium propionate) tolerance in baker's yeast. Absent any evidence to contrary and based on the combined teachings of the cited references there would have been a reasonable expectation of success in developing the claimed *Saccharmyces cerevisiae* strains.

Response to Arguments

Applicants arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants have analyzed and judged the elements as discussed by R1 and have characterized the yeast strains used for developing new hybrids
 - a. Although R1 does not disclose the method or elements used in the method as presently claimed, it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) . Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

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Therefore, absent evidence of criticality regarding the presently claimed process and given that R1 meets the requirements of the claimed tolerance to sugar and gas produce upon fermentation, R1 clearly meet the requirements of the present claims.

Furthermore, Applicants have tried to equate their control reference yeast, i.e. NCYC 996 to the sugar tolerant strain disclosed by R1 and conclude that since the developed strain of R1 is only as good as their control reference, then Applicants strain, also being claimed as sugar tolerant, is better than the strain disclosed by R1. Applicants contend that the NCYC 996 strain, used as their reference, is the inventive strain of US patent 4,396,632. They have calculated the amount of CO₂ evolved due to fermentation and conclude that since the amount of CO₂ by NCYC is more or less the same as CO₂ evolved by the strain disclosed by R1, then NCYC is as good as the strain disclosed by R1.

There are a few points that the Applicants have not taken into consideration when they calculated the CO₂ evolved.

- a. The flours used in the experiments by R1 and NCYC 996 are not the same.
- b. The dough of NCYC 996 comprises ammonium sulfate, which is absent in the dough of R1.
- c. The sugar content of the dough in NCYC 996 tests, % by weight, is 13.38% while that of R1 dough is 16.17%.
- d. The water in NCYC 996 dough is 75 parts per 100 parts of flour while that of R1 is 52 parts per 100 parts of the flour.

It is clear that NCYC cannot and should not be compared to the developed strain of R1. The NCYC 996 is not as good as the developed strain of R1.

Previously, it was mentioned to the Applicants that in their experiments they employed a higher yeast content for their doughs leading to shorter proof times.

In previous Office actions it was discussed and explained that experiments of the prior art and those as presently carried out cannot/should not be compared because of various factors involved. The dough as disclosed by Satoshi is a different dough, the controls are different for Satoshi experiments and the proof time, as presently claimed, cannot be simply compared to the volume of carbon dioxide evolve as disclosed by Satoshi.

Satoshi reports the volume of carbon dioxide in a dough comprising only 4 components. The amount of carbon dioxide evolved in these experiments is being compared to decrease in proof time, as presently claimed, of a dough comprising many other ingredients. The dough fermentation and the resulting carbon dioxide generation is a function of dough ingredients. One cannot compare tow different systems together and conclude that the claimed invention is more efficient.

2. Applicants have used the same reasoning to state that the NCYC 996 used as their reference is as good as the inventive yeast of Ando et al. They further contend that at 25% sugar, Ando's strain is as good as a regular yeast, therefore, it is as good as their reference strain.

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a. The inventive strain of Ando et al., P-712, has a sugar tolerance above 30-40% (baker's percent). Furthermore, the inventive yeast of Ando at 50% sugar (baker's percent) produces almost 3 times as much CO₂ as does the regular yeast strain. Therefore, Ando's yeast has a much higher sugar tolerance than what is presently claimed. Please see Col. 6; Table 2 of Ando.

3. Applicants argue that the yeast of R2 grown in the presence of organic acids does not have sugar in its dough.

a. The method of R2 discloses that yeasts can be made tolerant to the fungicidal effect of short chain organic acids when grown in the presence of such acids. Therefore, any baker's yeast when propagated in the presence of short chain organic acids (i.e. C₂-C₄) will be more tolerant to the fungicidal activity of such acids. Applicants are taking advantage of the same technique to claim a yeast which tolerates weak organic acids recited in claim 23. Developing such an acid tolerant strain is obvious in view of the teachings of R2.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1781

HAMID R BADR
Examiner
Art Unit 1781